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Yvette Alvarez-Perez — March 24, 2004 (Date)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Appl. No. : 09/939,532
Applicant : Michael Damm et al.
Filed : August 24, 2001
Title : METHOD FOR THE SYNTHESIS OF PEPTIDE SALTS, THEIR USE AND THE PHARMACEUTICAL PREPARATIONS CONTAINING PEPTIDE SALTS

TC/A.U. : 1654
Examiner : Gupta, Anish

Docket No. : 103832-401-NP

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

AMENDMENT

Sir:

This is in response to the Final Office Action dated September 24, 2003, for which a reply was due on December 24, 2003 and for which a three-month extension of time is requested to extend the time for response from December 24, 2003 to March 24, 2004. A Petition for Extension of Time under 37 CFR 1.136(a) with an appropriate extension fee is enclosed. To permit Examiner time to respond to this Amendment, Applicants have filed a Notice of Appeal concurrently.

Applicants respectfully request reconsideration of the above-identified patent application in view of the following amendments and remarks:

Amendments to the Claims are reflected in the listing of claims which begins on page 2 of this paper.

Remarks begin on page 3 of this paper.

AMENDMENTS TO THE CLAIMS:

This listing of claims will replace all prior versions, and listings, of claims in the application:

Listing of Claims:

Claim 1 (previously presented) A method for making a composition containing a peptide salt having a pharmaceutically acceptable anion comprising:

contacting a first peptide salt with a diluent to form a diluent solution;

contacting the diluent solution containing the first peptide salt with a mixed bed ion exchanger, wherein the mixed bed ion exchanger has strongly acidic cations and strong anion exchangers;

separating the mixed bed ion exchanger from the diluent solution;

contacting the diluent solution with an acid having a pharmaceutically acceptable anion, thereby forming an acid addition salt of the peptide having the pharmaceutically acceptable anion;

adding an adjuvant to the diluent solution; and

separating the diluent from the diluent solution.

Claim 2 (previously presented) The method of claim 1, wherein the first peptide salt is a salt of an LHRH antagonist selected from the group of Cetrorelix, Teverelix, Abarelix, Ganirelix, Azaline B, Antide, A-75998, Detirelix, Ramorelix, and RS-68439.

Claim 3 (previously presented) The method of claim 1, wherein said acid is embonic acid, stearic acid. or salicylic acid.

Claim 4 (previously presented) The method of claim 1, wherein the first peptide salt is Cetrorelix acetate. and said acid is embonic acid, and the peptide:acid molar ratio is 2:1.

Claim 5 (previously presented) The method of claim 1, wherein said acid addition salt of the peptide is separated from the diluent by freeze drying.

Claim 6-12 (cancelled)

REMARKS

Claims 1-5, which were all indicated as allowed in the Final Office Action, remain in this application. Rejected claims 6, 7 and 9-12 have been canceled. As requested by the Examiner, a PTO/SB/08 form (substitute for form 1449/PTO) is enclosed herewith listing the three prior art references that were cited on a PTO/SB/08 form previously submitted by Applicants but crossed out by the Examiner. It is respectfully submitted that the application is in condition for allowance and accordingly, allowance of the application is respectfully requested.

Should the Examiner require or consider it advisable that the specification and/or claims be further amended or corrected in formal respects in order to place the case in condition for final allowance, then it is respectfully requested that such amendment or correction be carried out by Examiner's Amendment and the case passed to issue. Alternatively, should the Examiner feel that a personal discussion might be helpful in advancing this case to allowance, the Examiner is invited to telephone the undersigned.

The Commissioner is authorized to charge any required fees, including any extension and/or excess claim fees, any additional fees, or credit any overpayment, to Goodwin Procter LLP Deposit Account No. 06-0923.

Respectfully submitted for Applicants,

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Dated: March 24, 2004